IntraStent® DoubleStrut™ Stent

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The IntraStent® DoubleStrut™ Stent is balloon expandable and intended for permanent implant. The stent is made from a 316L stainless steel tube cut into an open lattice design. Its design allows it to be crimped onto a non-compliant percutaneous transluminal angioplasty (PTA) balloon catheter. After mounting onto a balloon catheter, the stent is advanced to span the lesion and then expanded and deployed by inflating the balloon.

INDICATIONS AND USAGE

The IntraStent® DoubleStrut™ Stent is indicated for improving luminal diameter in patients with symptomatic atherosclerotic disease of the common and/or external iliac arteries up to 100 mm in length, with a reference vessel diameter of 5 to 10 mm.

CONTRAINDICATIONS

There are no contraindications known at this time based on the clinical data.

WARNINGS

- Persons with known allergic reactions to 316L stainless steel may suffer an allergic response to this device.

PRECAUTIONS

- The device should only be used by physicians who are trained in such interventional techniques as percutaneous transluminal angioplasty and placement of intravascular stents.
- Before insertion of the dilation catheter, the appropriate antiplatelet and anticoagulant therapy should be administered. Aspirin may be used as antiplatelet therapy. Consideration should be given to the risks and benefits of use in patients with history of reaction to antiplatelet and/or anticoagulant therapy.
- Consideration should be given to the risks and benefits of use in patients with history of severe reaction to contrast agents.
- The long-term outcome following repeat dilation of endothelialized stents is unknown at present.
- Stents should be used in pregnant women only if the potential benefit justifies the potential risk to the embryo or fetus.
- Safety and effectiveness has not been demonstrated in:

    - Patients who exhibit persistent acute intraluminal thrombus of the proposed lesion site, post thrombolytic therapy.
    - Perforation at the angioplasty site evidenced by extravasation of contrast media.
    - Aneurysm of the artery to be treated.
    - Restenotic lesion previously treated with a stent.
    - Pediatric patients

Stent Handling

- The stent is provided STERILE for one use only and should be used by the "Use Before Date" printed on the package.
- Carefully inspect the sterile package and stent prior to use to verify that neither has been damaged during shipment.

Stent Placement

- The vessel should be pre-dilated with an appropriate sized balloon.
- Overstretching of the artery may result in rupture and life threatening bleeding. Do not overstretch the stent. The inflation diameter of the balloon used during stent delivery should approximate the diameter of the artery at the intended implant site.
- The balloon inflation pressure should not exceed the maximum inflation pressure recommended by the manufacturer. An inflation device with a manometer is recommended.

- Do not retract the balloon (catheter) unless the balloon is fully deflated under vacuum.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage. The stent system and the guide catheter should be removed as a single unit.
- Implanting the stent across a bifurcation or side branch may result in occlusion of the artery and prevent further access for future transluminal interventions.
- Care should be taken during stent deployment to avoid extensive stent placement beyond the iliac artery into the aorta.
- When treating multiple lesions, reduce the chance of stent dislodgement by stenting the most distal lesion first followed by the stenting of proximal lesions.
- When more than one stent is required, resulting in stent to-stent contact, stent materials should be of similar composition to avoid the possibility of dissimilar metal corrosion.

Stent/System Removal

- If unusual resistance is felt at any time during lesion access before stent implantation, the stent system and the guide catheter should be removed as a single unit.
- If resistance occurs after the stent has exited the sheath or if the stent cannot be delivered to the appropriate target lesion, attempting to retract the stent/delivery assembly into the sheath may result in stent dislodgement. The sheath and stent/delivery assembly should be withdrawn as described below:

  1. Under fluoroscopic guidance, retract the stent to the exit of the sheath.
  2. Inflate the delivery balloon 1/2 to 1 atmosphere to help reduce the likelihood of stent dislodgement.
  3. While preserving the guidewire position, retract the sheath and stent/delivery assembly.
  4. Withdraw the sheath and stent/delivery assembly together.

Post Stent Placement

- The IntraStent DoubleStrut stent has not been tested for safety in the MR environment. Therefore, MRI scans should not be performed on patients post-implantation until the stent has completely endothelialized to minimize the potential for migration. For a conventional uncoated 316L stainless steel stent, this period is usually considered to be 8 weeks. This device has not been evaluated for heating in the MR environment. The effect of heating in the MR environment for overlapping stents or stents with fractured struts is not known. MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.
- Recrossing of newly implanted stents (with other devices) should be done very carefully; it may damage stent architecture or cause stent dislodgement.
- In clinical trials of the IntraStent DoubleStrut Stent, aspirin and Plavix was administered pre-procedure for a period of 3 months post-procedure.

OVERVIEW OF CLINICAL STUDIES

A multi-center, randomized, concurrently controlled study was conducted at 23 sites in the US. The primary objective of this study was to assess the performance of the IntraStent DoubleStrut Stent with use of the Cordis Opta 5™ or Boston Scientific Marshal™ stent delivery balloons compared with commercially available stents (WALLSTENT® Endoprosthesis or PALMAZ® stent), in patients with lesions in the common and/or external iliac artery. A total of 228 patients were enrolled; patients with a suboptimal PTA result during the treatment of a lesion in the common and/or external iliac artery were randomized between the two treatment groups. One hundred fifteen (115) patients were randomized to receive the IntraStent DoubleStrut Stent while 113 patients were randomized to receive the commercially available stents.

ADVERSE EVENTS

Observed Adverse Events

Table 1(Evaluable) and Table 2 (Intent-to-Treat) below summarize major adverse events reported in both treatment groups to 9 months. There have been 17 deaths reported. One control group (Palmaz stent) patient died within the first 30 days of an undetermined cause. An additional nine control group patients (eight Palmaz and one Wallstent stents) died during follow-up (511, 529, 551, 599, 617, 722, 1032, 1277, 1290 days post-procedure); two of myocardial infarction (MI), three of cancer, one of cardiopulmonary arrest, one of cardiogenic shock, one of congestive heart failure (CHF) and one undetermined. Seven treatment group patients died during follow-up (201, 331, 391, 517, 542, 719, 1183 days post-procedure); one of MI, three of cancer, one of chronic obstructive pulmonary disease (COPD) exacerbation, one of cerebro-vascular accident (CVA) and one of sepsis.

Table 1. Major Observed Adverse Events (Evaluable)

Description of Event	IntraStent DoubleStrut Stent	Control Stents	Difference (95% CI)	P-Value
Complications ≤ 30 days				
Total Complications < 30 Days	2.7% (3/113)	8.9% (10/112)	6.3% [0.2%, 12.3%]	0.04
MAIE	0.0% (0/113)	2.7% (3/112)	2.7% [-0.3%, 5.7%]	0.08
Death within 30 Days	0.0% (0/113)	0.9% (1/112)	0.9% [-0.8%, 2.6%]	0.32
MI (in hospital)	0.0% (0/113)	0.0% (0/112)	0.0% [0.0%, 0.0%]	.
Amputation of Target Limb	0.0% (0/113)	0.9% (1/112)	0.9% [-0.8%, 2.6%]	0.32
Target vessel revascularization	0.0% (0/113)	0.9% (1/112)	0.9% [-0.8%, 2.6%]	0.32
Stent Thrombosis	0.0% (0/113)	0.9% (1/112)	0.9% [-0.8%, 2.6%]	0.32
Major bleeding complication	0.9% (1/113)	3.6% (4/112)	2.7% [-1.2%, 6.5%]	0.17
Major vascular complication	0.9% (1/113)	1.8% (2/112)	0.9% [-2.1%, 3.9%]	0.56
Renal Insufficiency	0.0% (0/113)	0.9% (1/112)	0.9% [-0.8%, 2.6%]	0.32
Dissection	0.9% (1/113)	2.7% (3/112)	1.8% [-1.7%, 5.2%]	0.31
Stroke	0.9% (1/113)	0.0% (0/112)	-0.9% [-2.6%, 0.8%]	0.32
MI	0.0% (0/113)	0.0% (0/112)	0.0% [0.0%, 0.0%]	.
Complications > 30 days (to 9 Months)				
Total Complications > 30 Days	6.6% (7/106)	5.9% (6/102)	-0.7% [-7.3%, 5.9%]	0.83
MAIE	3.8% (4/106)	2.0% (2/102)	-1.8% [-6.3%, 2.7%]	0.43
Death within 30 Days	0.0% (0/113)	0.9% (1/112)	0.9% [-0.8%, 2.6%]	0.32
MI (in hospital)	0.0% (0/106)	0.0% (0/102)	0.0% [0.0%, 0.0%]	.
Amputation of Target Limb	0.9% (1/106)	0.0% (0/102)	-0.9% [-2.8%, 0.9%]	0.32
Target vessel revascularization	4.7% (5/106)	2.9% (3/102)	-1.8% [-7.0%, 3.4%]	0.50
Death	0.9% (1/106)	0.0% (0/102)	-0.9% [-2.8%, 0.9%]	0.32
Stent Thrombosis	0.0% (0/106)	1.0% (1/102)	1.0% [-0.9%, 2.9%]	0.32
Major bleeding complication	0.9% (1/106)	1.0% (1/102)	0.0% [-2.6%, 2.7%]	0.98
Major vascular complication	0.0% (0/106)	0.0% (0/102)	0.0% [0.0%, 0.0%]	.
Renal Insufficiency	0.0% (0/106)	0.0% (0/102)	0.0% [0.0%, 0.0%]	.
Dissection	0.0% (0/106)	0.0% (0/102)	0.0% [0.0%, 0.0%]	.
Stroke	0.0% (0/106)	0.0% (0/102)	0.0% [0.0%, 0.0%]	.
MI	0.0% (0/106)	1.0% (1/102)	1.0% [-0.9%, 2.9%]	0.32
Cumulative Complications (to 9 Months)				
Total Complications - Combined	9.4% (10/106)	15.7% (16/102)	6.3% [-2.7%, 15.2%]	0.18
MAIE	3.8% (4/106)	4.9% (5/102)	1.1% [-4.4%, 6.7%]	0.69
Death within 30 days	0.0% (0/113)	0.9% (1/112)	0.9% [-0.8%, 2.6%]	0.32
MI (in hospital)	0.0% (0/106)	0.0% (0/102)	0.0% [0.0%, 0.0%]	.
Amputation of Target Limb	0.9% (1/106)	1.0% (1/102)	0.0% [-2.6%, 2.7%]	0.98
Target vessel revascularization	4.7% (5/106)	3.9% (4/102)	-0.8% [-6.3%, 4.7%]	0.78
Death	0.9% (1/106)	1.0% (1/102)	0.0% [-2.6%, 2.7%]	0.98
Stent Thrombosis	0.0% (0/106)	2.0% (2/102)	2.0% [-0.7%, 4.7%]	0.16
Major bleeding complication	1.9% (2/106)	4.9% (5/102)	3.0% [-1.9%, 7.9%]	0.23
Major vascular complication	0.9% (1/106)	2.0% (2/102)	1.0% [-2.2%, 4.3%]	0.54
Renal Insufficiency	0.0% (0/106)	1.0% (1/102)	1.0% [-0.9%, 2.9%]	0.32
Dissection	0.9% (1/106)	2.9% (3/102)	2.0% [-1.8%, 5.8%]	0.30
Stroke	0.9% (1/106)	0.0% (0/102)	-0.9% [2.9%, -0.9%]	0.32
MI	0.0% (0/106)	1.0% (1/102)	1.0% [-0.9%, 2.9%]	0.32

Subjects were counted once for multiple occurrences of an adverse event
MAIE (Major Adverse Ischemic Event) = Any death within 30 days, MI (in-hospital), amputation of target limb or target vessel revascularization (TVR).
Major Complication = Includes death, stroke, bleeding requiring transfusion, myocardial infarction, embolism, or any complication that is procedure or device related which requires a surgical procedure, interventional procedure or extended hospital stay.
Difference = Control – Treatment; SE=sqrt(p1*q1/n1+p2*q2/n2) CI=Diff±1.96*SE

Table 2. Major Observed Adverse Events (Intent-to-Treat)

Description of Event	IntraStent DoubleStrut Stent (n=115)	Control Stents (n=113)	Difference (95% CI)	P-Value
Complications ≤ 30 days				
Total complications ≤ 30 days	2.6% (3/115)	8.8% (10/113)	6.2% [0.3%, 12.2%]	0.04
MAIE	0.0% (0/115)	2.7% (3/113)	2.7% [-0.3%, 5.6%]	0.08
Death within 30 days	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31

23

Description of Event	IntraStent DoubleStrut Stent (n=115)	Control Stents (n=113)	Difference (95% CI)	P-Value
MI (in-hospital)	0.0% (0/115)	0.0% (0/113)	0.0% [0.0%, 0.0%]	--
Amputation of target limb	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31
Target vessel revascularization	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31
Stent thrombosis	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31
Major bleeding complication	0.9% (1/115)	3.5% (4/113)	2.7% [-1.1%, 6.5%]	0.17
Major vascular complication	0.9% (1/115)	1.8% (2/113)	0.9% [-2.1%, 3.9%]	0.55
Renal insufficiency	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31
Dissection	0.9% (1/115)	2.7% (3/113)	1.8% [-1.6%, 5.2%]	0.31
Stroke	0.9% (1/115)	0.0% (0/113)	-0.9% [-2.6%, 0.8%]	0.32
MI	0.0% (0/115)	0.0% (0/113)	0.0% [0.0%, 0.0%]	--
Complications > 30 days (to 9 Months)				
Total complications > 30 days	6.1% (7/115)	5.3% (6/113)	-0.8% [-6.8%, 5.2%]	0.80
MAIE	3.5% (4/115)	1.8% (2/113)	-1.7% [-6.9%, 2.4%]	0.42
Death within 30 days	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31
MI (in-hospital)	0.0% (0/115)	0.0% (0/113)	0.0% [0.0%, 0.0%]	--
Amputation of target limb	0.9% (1/115)	0.0% (0/113)	-0.9% [-2.6%, 0.8%]	0.32
Target vessel revascularization	4.3% (5/115)	2.7% (3/113)	-1.7% [-6.5%, 3.1%]	0.48
Death	0.9% (1/115)	0.0% (0/113)	-0.9% [-2.6%, 0.8%]	0.32
Stent thrombosis	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31
Major bleeding complication	0.9% (1/115)	0.9% (1/113)	-0.0% [-2.4%, 2.4%]	0.99
Major vascular complication	0.0% (0/115)	0.0% (0/113)	0.0% [0.0%, 0.0%]	--
Renal insufficiency	0.0% (0/115)	0.0% (0/113)	0.0% [0.0%, 0.0%]	--
Dissection	0.0% (0/115)	0.0% (0/113)	0.0% [0.0%, 0.0%]	--
Stroke	0.0% (0/115)	0.0% (0/113)	0.0% [0.0%, 0.0%]	--
MI	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31
Cumulative Complications (to 9 Months)				
All combined	8.7% (10/115)	14.2% (16/113)	5.5% [-2.8%, 13.7%]	0.20
MAIE	4.3% (5/115)	4.4% (5/113)	0.1% [-5.2%, 5.4%]	0.98
Death within 30 days	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31
MI (in-hospital)	0.0% (0/115)	0.0% (0/113)	0.0% [0.0%, 0.0%]	--
Amputation of target limb	0.9% (1/115)	0.9% (1/113)	0.0% [-2.4%, 2.4%]	0.99
Target vessel revascularization	4.3% (5/115)	3.5% (4/113)	-0.8% [-5.9%, 4.2%]	0.75
Death	0.9% (1/115)	0.9% (1/113)	-0.0% [-2.4%, 2.4%]	0.99
Stent thrombosis	0.0% (0/115)	1.8% (2/113)	1.8% [-0.7%, 4.2%]	0.15
Major bleeding complication	1.7% (2/115)	4.4% (5/113)	2.7% [-1.8%, 7.2%]	0.24
Major vascular complication	0.9% (1/115)	1.8% (2/113)	0.9% [-2.1%, 3.9%]	0.55
Renal insufficiency	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31
Dissection	0.9% (1/115)	2.7% (3/113)	1.8% [-1.6%, 5.2%]	0.31
Stroke	0.9% (1/115)	0.0% (0/113)	-0.9% [-2.6%, 0.8%]	0.32
MI	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31

Subjects were counted once for multiple occurrences of an adverse event.
MAIE (Major Adverse Ischemic Event) = Any death within 30 days, MI (in-hospital), amputation of target limb or TVR.
Major Complication = Includes death, stroke, bleeding requiring transfusion, myocardial infarction, embolism, or any complication that is procedure or device related which requires a surgical procedure, interventional procedure or extended hospital stay.
Difference = Control – Treatment; SE=sqrt(p1*q1/n1+p2*q2/n2) CI=Diff±1.96*SE

Potential Adverse Events

The following anticipated adverse events have been identified as possible complications of intravascular stent implantation:

- Allergic/anaphylactoid reaction
- Aneurysm
- Angina/coronary ischemia
- Arterial occlusion/thrombus, at puncture site or remote
- Arterial occlusion/restenosis of the treated vessel
- Arteriovenous fistula
- Arrhythmia
- Death related/unrelated to procedure
- Embolization, arterial or other
- Hematoma
- Hypotension/hypertension
- Intimal injury/dissection
- Ischemia/infarction of tissue/organ
- Local infection
- Malposition (failure to deliver the stent to intended site)
- Migration
- Pulmonary embolism
- Pseudoaneurysm
- Renal failure
- Septicemia/bacteremia
- Stent fever
- Vasospasm
- Venous occlusion/thrombus at puncture site or remote

CLINICAL STUDIES

Objective/Study Endpoints: The primary efficacy endpoint was death within 30 days or primary patency failure at 9 months. Primary patency failure included any restenosis (≥50%) or TVR. The primary safety endpoint was overall major complication rate at 30-days. Major complications includes death, stroke, bleeding requiring transfusion, myocardial infarction, embolism or any complication that is procedure related or device related which requires a surgical procedure, interventional procedure or an extended stay. Secondary endpoints included acute angiographic success and individual major complication rate at 30 days.

Conclusions: Based on analysis of 1) primary patency failure or 2) death within 30 days of the procedure, there was no difference between outcomes for patients receiving either the IntraStent DoubleStrut Stent vs. the control stents after suboptimal PTA of a lesion in the iliac artery.

Design:
This study was a prospective, multi-center, randomized controlled clinical trial. The control group consisted of Wallstent® and Palmaz® stents. Patients were eligible for the study if they had been diagnosed with atherosclerotic peripheral disease of the iliac artery of diameter 5-10mm and length ≤100mm. Follow-up was required at post-intervention, 3 months, 9 months, 12 months, and every 12 months thereafter. At post-intervention, 3 month, 12 month and yearly follow-up intervals, confirmation of patency was required. At 9 month follow-up, duplex scan was required and patency was assessed by confirmation that the peak systolic velocity on the duplex scan had not doubled within the treated artery.

Patients Studied: Eligible patients had lesions in the common and external iliac artery of up to 100 mm in length with a documented suboptimal PTA result, and a reference vessel diameter of 5 to 10 mm. Baseline characteristics for the patients are presented in Table 3.

Table 3. Baseline Characteristics
All randomized U.S. patients (n=228)

Characteristics	IntraStent DoubleStrut Stent (n=115)	Control Stents (n=113)	Difference [95% CI]	P-Value
Age (yrs), mean±SD (N)	62 ± 10	65 ± 10	-2.5 (-0.106,5.158)	0.06
Number of men	65% (75/115)	64% (72/113)	1.5% (-11.1%,14.1%)	0.81
History of smoking	82% (94/115)	77% (87/113)	4.8% (-5.9%,15.4%)	0.65
History of diabetes mellitus	23% (26/115)	27% (30/113)	-3.9% (-15.2%,7.3%)	0.49
Reference vessel diameter (mm), mean±SD (N)	7.6 ± 1.4 (115)	7.6 ± 1.2 (113)	-0.04 (-0.39,0.31)	0.83
Lesion length (mm), mean±SD (N)	30 ± 18 (115)	29 ± 17 (113)	0.5 (-4.0,5.0)	0.83

Numbers are % (counts/sample size) or Mean±SD

Methods: Informed consent, baseline demographics and medical history data were collected prior to treatment. Patients eligible for the study underwent a PTA and were randomized following an angiographically documented suboptimal result defined by the presence of an unfavorable lesion morphology such as: a) a documented inadequate angiographic and/or hemodynamic result as defined by a 30% or greater residual stenosis subsequent to PTA, lesion recoil or intimal flaps and/or b) flow limiting dissections post PTA longer than the initial lesion length, and/or c) a 5 mm Hg or greater mean transtenotic pressure gradient post PTA. Only one limb could be enrolled in the study. Baseline quantitative angiography was performed pre-procedure, post-PTA, and post-procedure in all patients.

Clinical follow-up visits were conducted at post-intervention, 1, 3, 9 and 12 months post-procedure and yearly thereafter. Patients were recommended to receive aspirin (325 mg/day) for at least 3 months following hospital discharge. Duplex Ultrasound was utilized in all patients to make a determination of restenosis at the 9-month follow-up. If Duplex Ultrasound was nondiagnostic, a confirmatory angiogram was performed to document the amount of restenosis present. If angiogram was not done then patency was determined by non-invasive testing (segmental pressure, Doppler wave

recording, etc.) if possible. An independent clinical events committee adjudicated all of the major vascular adverse events and deaths. Computer assisted quantitative angiographic analysis (QA), Duplex Ultrasound, non-invasive Doppler wave recording or pulse volume recording, and angiographic measurements were analyzed at independent central laboratories and primary endpoint determination was based on these results.

Results: Follow-up compliance through 9 months was 91.3% (105/115) vs. 89.4% (101/113) in the treatment vs. control groups, respectively, of the returning patients. Based on analysis of 1) primary patency failure (which includes 9-month restenosis and TVR) or 2) death within 30 days of the procedure, there was no difference between outcomes for patients receiving either the IntraStent DoubleStrut Stent vs. the control stents after suboptimal PTA of a lesion in the iliac artery (10.4% vs. 9.8%, p=0.89). The principal effectiveness and safety results are presented in Table 4 (Evaluable) and Table 5 (Intent-to-Treat). Freedom from target lesion revascularization (TLR) events Kaplan-Meier curve is presented in Figure 1.

Table 4. Principal Effectiveness and Safety Results (Evaluable)
All randomized U.S. patients (n=228)

EFFICACY MEASURES	IntraStent DoubleStrut Stent (n=115)	Control Stents (n=113)	Difference [95% CI]	P-Value
Primary Efficacy Endpoint	10.4% (10/96)	9.8% (10/102)	-0.6% [-9.0%, 7.8%]	0.89
9-month restenosis	7.4% (7/95)	6.1% (6/99)	-1.3% [-8.4%, 5.7%]	0.71
Death within 30 days	0.0% (0/112)	0.9% (1/112)	0.9% [-0.8%, 2.6%]	0.31
9-month TVR	4.8% (5/104)	4.0% (4/100)	-0.8% [-6.4%, 4.8%]	0.79
Acute Procedural Success	94.6% (105/111)	89.2% (99/111)	-5.4% [-12.6%,1.7%]	0.14
Primary Patency to 9 Months	90.6% (87/96)	92.0% (92/100)	1.4% [-6.5%, 9.3%]	0.73
Bypass within 9 Months	1.8% (2/112)	0% (0/112)	-1.8% [-4.2%, 0.7%]	0.16
TLR-free at 9 Months**	98.2% [95.7%, 100.0%]	99.1% [97.3%, 100.0%]	1.96 [0.18, 21.65]	--
SAFETY MEASURES				
Major Complications ≤ 30 days	2.7% (3/113)	8.9% (10/112)	6.3% [0.2%, 12.3%]	0.04
MAIE ≤ 30 days	0.0% (0/113)	2.7% (3/112)	2.7% [-0.3%, 5.7%]	0.08
Combined MAIE to 9 Months	4.7% (5/106)	4.9% (5/102)	0.2% [-5.6%, 6.0%]	0.95
Stent thrombosis	0.0% (0/106)	2.0% (2/102)	2.0% [-0.7%, 4.7%]	0.16
Major bleeding complications	1.9% (2/106)	4.9% (5/102)	3.0% [-1.9%, 7.9%]	0.23
Major vascular complications	0.9% (1/106)	2.0% (2/102)	1.0% [-2.2%, 4.3%]	0.54
Stroke	0.9% (1/106)	0.0% (0/102)	-0.9% [-2.8%, 0.9%]	0.32
MI	0.0% (0/106)	1.0% (1/102)	1.0% [-0.9%, 2.9%]	0.32

** Kaplan-Meier survival analysis, percent and confidence intervals followed by relative-risk with associated confidence interval from Cox proportional hazards regression.
Numbers are % (counts/sample size)
Difference = Control – Treatment; SE=sqrt(p1*q1/n1+p2*q2/n2) CI=Diff±1.96*SE
Primary Efficacy Endpoint = 1) primary patency failure at 9 months that includes restenosis (≥50%) or TVR or 2) peri-procedural (30 days) death
Acute Procedural Success = Patients with <30% stenosis immediately after the procedure and no major complications during the procedure
MAIE = death to 30 days, in-hospital MI, TVR or amputation
Primary patency = uninterrupted patency of the limb with no procedure performed on or at the margins of the treated segment
Bypass = reestablishment of flow to distal arteries following bypass of target vessel.
Major Complication = Includes death, stroke, bleeding requiring transfusion, myocardial infarction, embolism, or any complication that is procedure or device related which requires a surgical procedure, interventional procedure or extended hospital stay.

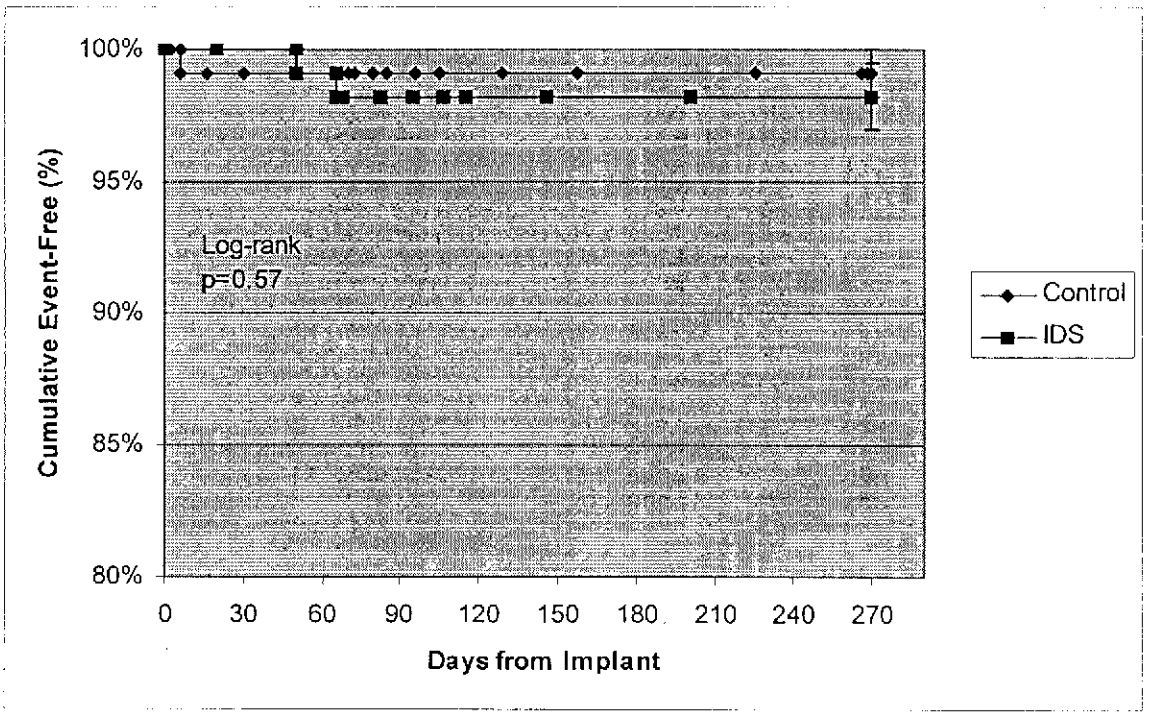
Table 5. Principal Effectiveness and Safety Results (Intent-to-Treat)
All randomized U.S. patients (n=228)

EFFICACY MEASURES	IntraStent DoubleStrut Stent (n=115)	Control Stents (n=113)	Difference [95% CI]	P-Value
Primary Efficacy Endpoint	8.7% (10/115)	8.8% (10/113)	0.2% [-7.2%, 7.5%]	0.97
9-month restenosis	6.1% (7/115)	5.3% (6/113)	-0.8% [-6.8%, 52%]	0.80
Death within 30 days	0.0% (0/115)	0.9% (1/113)	0.9% [-.8%, 2.6%]	0.31
9-month TVR	4.3% (5/115)	3.5% (4/113)	-0.8% [-5.9%, 4.2%]	0.75
Acute Procedural Success	91.3% (105/115)	87.6% (99/113)	-3.7% [-11.7%,4.3%]	0.37
Primary Patency to 9 Months	75.7% (87/115)	81.4% (92/113)	5.8% [-4.9%, 16.4%]	0.29

Bypass within 9 Months	1.7% (2/115)	0% (0/113)	-1.7% [-4.1%, 0.7%]	0.16
TLR-free at 9 Months**	98.2% [95.7%, 100.0%]	99.1% [97.3%, 100.0%]	1.96 [0.18, 21.65]	--
SAFETY MEASURES				
Major Complications ≤ 30 days	2.6% (3/115)	8.8% (10/113)	6.2% [0.3%, 12.2%]	0.04
MAIE ≤ 30 days	0.0% (0/115)	2.7% (3/113)	2.7% [-0.3%, 5.6%]	0.08
Combined MAIE to 9 Months	4.3% (5/115)	4.4% (5/113)	0.1% [-5.2%, 5.4%]	0.98
Stent thrombosis	0.0% (0/115)	1.8% (2/113)	1.8% [-0.7%, 4.2%]	0.15
Major bleeding complications	1.7% (2/115)	4.4% (5/113)	2.7% [-1.8%, 7.2%]	0.24
Major vascular complications	0.9% (1/115)	1.8% (2/113)	0.9% [-2.1%, 3.9%]	0.55
Stroke	0.9% (1/115)	0.0% (0/113)	-0.9% [-2.6%, 0.8%]	0.32
MI	0.0% (0/115)	0.9% (1/113)	0.9% [-0.8%, 2.6%]	0.31

** Kaplan-Meier survival analysis, percent and confidence intervals followed by relative-risk with associated confidence interval from Cox proportional hazards regression.
Numbers are % (counts/sample size)
Difference = Control – Treatment; SE=sqrt(p1*q1/n1+p2*q2/n2) CI=Diff±1.96*SE
Primary Efficacy Endpoint = 1) primary patency failure at 9 months that includes restenosis (≥50%) or TVR or 2) peri-procedural (30 days) death
Acute Procedural Success = Patients with <30% stenosis immediately after the procedure and no major complications during the procedure
MAIE = death to 30 days, in-hospital MI, TVR or amputation
Primary patency = uninterrupted patency of the limb with no procedure performed on or at the margins of the treated segment
Bypass = reestablishment of flow to distal arteries following bypass of target vessel.
Major Complication = Includes death, stroke, bleeding requiring transfusion, myocardial infarction, embolism, or any complication that is procedure or device related which requires a surgical procedure, interventional procedure or extended hospital stay.

Figure 1. Survival Free From Target Lesion Revascularization to 9 months (Event-Free Survival ±1.5 SE)



27

All Randomized Patients Treated With Survival Information (N=228)

	30 Day		90 Day		270 Day	
	IDS	Control	IDS	Control	IDS	Control
Number at risk	111	109	107	104	102	97
Cumulative number with event	0	1	2	1	2	1
Kaplan-Meier Estimate	100%	99.1%	98.2%	99.1%	98.2%	99.1%
Standard Error	N/A	0.009	0.013	0.009	0.013	0.009

DIRECTIONS FOR USE

1. Recommended Items for Implant

- Prepare the following items using sterile technique:
  - ♦ 10 cc syringe filled with sterile saline.
  - ♦ PTA balloon catheter, 0.035" 5Fr shaft or larger.
  - ♦ 0.035 exchange guidewire.
  - ♦ Inflation device.
  - ♦ Pre-deployment dilation catheter.
  - ♦ Appropriately sized hemostatic introducer sheath. The mounted stent will add approximately 1F to the balloon sheath French size described in the balloon manufacturer's Instruction for Use. As an example, a balloon requiring a 5F sheath plus 1F for the stent, allows a 6F sheath to be used (see box label).

2. Stent and PTA Balloon Catheter Assembly

- Select a stent and non-compliant PTA balloon dilation catheter with a nominal balloon diameter matching the reference lumen diameter of the artery. Additionally, the balloon length selected must be longer than the stent length.
- Remove the stent from the package and rinse in sterile saline.
- Remove the balloon catheter from the sterile package in preparation for stent mounting.
- Pre-inflate the balloon to ensure the balloon opens uniformly.
- Refold the balloon per manufacturer's instructions.
- Visually inspect the balloon to assure that it is properly folded to its lowest profile before stent application.
- If the balloon has a lubricious coating, use a saline saturated sterile gauze to gently wipe the folded balloon to reduce the lubricious coating.
- Carefully insert the distal tip of the unexpanded balloon, while maintaining balloon fold into the angled end of the stent mounting tube.

- While holding the cap of the mounting tube, gently pinch the mounting tube behind the stent and glide the stent onto the balloon. Do not compress the stent on the mounting tube. This may potentially crimp the stent to the mounting tube.

- Continue to slide the stent over the balloon while using the balloon radiopaque markers for centering the balloon.

- Gently using the thumbs and index fingers of both hands, crimp the stent onto the balloon from all directions to ensure full adherence of the stent to the balloon.
- Flush the balloon catheter lumen with saline, then load the stent/delivery assembly onto the guidewire.
- Pre-inflate the balloon with one-half to one atmosphere to slightly inflate both balloon cones.
- Maintain this low pressure during insertion of the stent/delivery assembly through the introducer sheath.

3. Stent Implantation

- The preferred access site is the common femoral artery.
- Predilate the lesion/vessel with appropriate diameter balloon.
- The stent/delivery assembly is advanced through the sheath, over the guidewire into correct position.
- **CAUTION:** If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage. The stent system and the guide catheter should be removed as a single unit.
- Position the stent across the target lesion. The distal portion of the stent should be positioned to completely cover the distal extent of the lesion. If more than one stent is required, the first should be positioned to completely cover the distal extent of the lesion.

  CAUTION: If resistance occurs after the stent has exited the sheath or if the stent cannot be delivered to the appropriate target lesion, attempting to retract the stent/delivery assembly into the sheath may result in stent dislodgement. The sheath and stent/delivery assembly should be withdrawn as described below:

  1. Under fluoroscopic guidance, retract the stent to the exit of the sheath.
  2. Inflate the delivery balloon one-half to one atmosphere to help reduce the likelihood of stent dislodgement.
  3. While preserving the guidewire position, retract the sheath and stent/delivery assembly.
  4. Withdraw the sheath and stent/delivery assembly together.
- Under fluoroscopy, expand the stent by inflating the balloon until the stent is fully expanded and no waist is noted (a mean of 9.4 atmospheres with a range of 3-20 atmospheres was exhibited during the trial). Do not exceed the balloon catheter manufacturer's recommended maximum balloon inflation pressure.
- Deflate the balloon catheter.
- Rotate the deflated balloon delivery catheter to ensure the stent is free and properly deployed.
- Remove the balloon catheter.
- Appropriate final expansion of the stent should be determined using angiography.

NOTE: The diameter of the stent may be increased post-placement by expanding with a larger diameter balloon. Do not exceed the maximum recommended expanded stent diameter of 10 mm.

- If the stent does not cover the lesion, a second stent should be implanted providing adequate overlapping of the initial implanted stent.